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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,076	11/08/1999	DENISA D. WAGNER	10861/011003	6116

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/16/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/436076	WAGNER ET AL.	
	Examiner	Art Unit	
	GAMBEL	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 7/17/02

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application. 40-41, 49-52, 59-60, 73-74

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) \_\_\_\_\_ is/are rejected. 40-41, 49-52, 59-60, 73-74

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### DETAILED ACTION

1. Applicant's amendment, filed 7/17/02 (Paper No. 25), has been entered.  
Claims 45 and 56 have been canceled.  
Claims 1-39, 42-44, 46-48, 53-55, 57-58 and 61-72 have been canceled previously.

Claims 40, 51 and 73-74 have been amended.

Claims 40-41, 49-52, 59-60 and 73-74 are pending.

Claims 40-41, 49-52, 59-60, 73-74 are being acted upon as the elected invention.

Claims 40-41, 49-52, 59-60, and 73-74, as they read on Groups I-III and V-XIII have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.  
This Office Action will be in response to applicant's arguments, filed 7/17/02 (Paper No. 25).  
The rejections of record can be found in the previous Office Action (Paper No. 24).
3. Upon reconsideration of applicant's amended claims, filed 7/17/02 (Paper No. 25), the previous rejections under 35 U.S.C. § 112, second paragraph, have been withdrawn.
4. Claims 73-74 are objected to given that the proper spelling of "restinosis" is "restenosis".
5. Claims 40-41, 49-52, 59-60, 73-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. Patent No. 6,309,639) in view of Tedder et al. (U.S. Patent No. 5,834,425) and Collier et al. (U.S. Patent No. 5,976,532) for the reasons of record set forth in Paper No. 24.

Applicant's arguments, filed 7/17/02 (Paper No. 25), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant asserts that the Cummings et al. reference does not disclose the PSGL-1 molecule and submits that the reference simply states that the described ligand is a 120 kD protein on columns 11-12 of the reference.

Applicant's arguments appear inconsistent in that it appears that applicant acknowledges that the Cummings et al. does teach antibodies to the P-selectin glycoprotein ligand. Therefore, applicant does acknowledged that Cummings et al. does teach the PSGL. Furthermore, the reference cites the P-selectin glycoprotein ligand in its disclosure, including the title.

Applicant has not proffered any objective evidence that the PSGL of the instant claims differs from the PSGL of the prior art.

Further, it is noted that products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Also, see U.S. Patent No. 6,124,267 which discloses PSGL-1 and claims priority to same priority documents of Cummings et al. U.S. Patent No. 6,309,639 of the prior art rejection.

Also, applicant submits that the inhibitory agent used in the reference for inhibiting inflammatory responses is an antibody to a P-selectin glycoprotein ligand.

However, the entire disclosure of a U.S. Patent having an earlier filing date can be relied on to reject the claims. See MPEP 2136.02.

Although applicant asserts that the prior art does not teach the treatment of atherosclerosis with chimeric PSGL-1 molecules, the combination of references does provide sufficient motivation and expectation of success in providing chimeric PSGL-1 to treat various disorders and conditions associated with platelet-leukocyte interactions including atherosclerosis and ischemia, myocardial infarction and reperfusion injury, encompassed by the claimed methods. For example, see Clinical Applications on columns 18-22 and Claims of Cummings et al.

Applicant acknowledges that Tedder et al. discloses that chimeric peptides can be formed from different selectins but asserts that applicant is claiming a method of using certain chimeric molecules to treat atherosclerosis and restenosis..

As pointed out previously, Tedder et al. teach the art known generation and use of chimeric peptides combining ligand binding portions of selecting based inhibitory therapeutics, including those based upon P-selectin, with other molecules such as immunoglobulin to increase serum half-life or avidity of the therapeutic agent to block platelet or leukocyte-mediated inflammation (see entire document, including Use on columns 10-14). Similar to Cummings et al. and art known practice at the time the invention was made, Tedder et al. teach combination therapy (see column 13, paragraph 1).

Given the art known practice and desire to increase the avidity and/or half-life of therapeutics in general, including selectin-mediated inhibitors, as taught by Tedder et al., one of ordinary skill in the art would have been motivated to modify the PSGL-1 and fragments thereof taught by Cummings et al. By making chimeric constructs thereof in the treatment of cardiovascular disorders.

Applicant asserts that there is no motivation to combine Collier et al. with Cummings et al. because Cummings et al. does not mention surgical procedures or chimeric molecules and Cummings et al. / Tedder et al. Are directed to inflammatory conditions which are not discussed in Collier et al.

Again, Cummings et al. teach the clinical applications, including atherosclerosis and ischemia, myocardial infarction and reperfusion injury, by inhibiting platelet-leukocyte interactions with PSGL-1 and fragments thereof (see entire document, including Clinical Applications on columns 18-22 and Claims). Cummings et al. teach that the therapeutic use that reduce leukocyte adherence in ischemic myocardium can significantly enhance the therapy efficacy of thrombolytic agents (see column 18, paragraph 7).

Also, as pointed out previously, Collier et al. teach the art known vessel-corrective techniques at the time the invention was made in the treatment of cardiovascular disorders such as atherosclerosis and restenosis, including angioplasty, atherectomy and coronary bypass surgery (see Background of the Invention on column 1 and Utility of Platelet-specific Chimeric Immunoglobulin on columns 5-7). In teaching the use of an inhibitor of platelet aggregation and thrombus formation associated with such conditions, Collier et al. teach the art known use of combination therapy with other drugs such as thrombolytic agents and that the amounts administered before, along with or subsequent to treatment will depend on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made (see column 6, paragraphs 2-3).

In contrast to applicant's assertions, Cummings et al. and Collier et al. are drawn to the same or similar methods of inhibiting platelet-leukocyte / endothelial interactions for various clinical applications, including atherosclerosis and ischemia, myocardial infarction and reperfusion injury as well as cardiovascular disorders such as atherosclerosis and restenosis, including angioplasty, atherectomy and coronary bypass surgery.

Given the art known practice of combination therapy, as taught by Cummings et al., Tedder et al. and Collier et al. as well as the art known practice of vessel-occlusive techniques to treat atherosclerosis and restenosis, as taught by Collier et al., one of ordinary skill in the art would have been motivated to administer the PSGL-1 and fragments thereof, as taught by Cummings et al. in various vessel-occlusive techniques given its properties of inhibiting platelet-leukocyte interactions for various clinical applications, including atherosclerosis and ischemia, myocardial infarction and reperfusion injury, as taught by Cummings et al. with an expectation of success.

Given the art known practice of modes of administrations and dosing depending on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made, as taught by Collier et al. In cardiovascular diseases, the claimed limitations were met or would have been obvious variants in meeting the needs of the patients in order to achieve a therapeutic effect depending on the symptom at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

Applicant's arguments are not found persuasive.

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

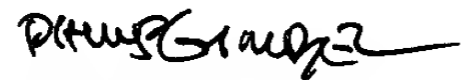
**7. No claim is allowed.**

**8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.**

Serial No. 09/436076  
Art Unit 1644

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.  
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September 13, 2002